Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 20368: Bismuth, [2-(hydroxy-κ*O*)propanoato-κ*O*][2-(hydroxy-κ*O*)propanoato(2-)-κ*O*]-, (*T*-4)- (Chemical Abstracts Service registry number 6591-53-3)

Regulatory decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance and have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance identity

The notified chemical is bismuth, [2-(hydroxy-κ*O*)propanoato-κ*O*][2-(hydroxy-κ*O*)propanoato(2-)-κ*O*]-, (*T*-4)- (Chemical Abstracts Service registry number[1] 6591-53-3).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in industrial coatings. No other uses are anticipated in Canada.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water, sediment and soil. The lactate portion of the substance is not expected to be persistent based on its potential for biodegradation; however, bismuth will be persistent. The substance is not expected to bioaccumulate based on the biodegradation potential of lactate and high adsorption potential of bismuth which will limit its bioavailability.

Environmental risk assessment

Based on the available hazard information, the substance has moderate to high acute toxicity to aquatic invertebrates (median lethal concentration (LC_{50}) <100 mg/L). Using the LC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 10 to account for acute to chronic extrapolation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 µg/L, which was used to estimate the ecological risk.

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The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from transportation and formulation by release of the substance to water resulting in predicted environmental concentrations (PECs) in the range of 1-10 µg/L and 0.01-0.1 µg/L, respectively. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 1-10 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause ecological harm in Canada.

Human health risk assessment

Based on the available hazard information, the substance has low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight) and is expected to have low subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level >100 mg/kg-bw/day). It is not expected to be a dermal sensitizer. It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial coatings, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water and air is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low toxicity and low potential for exposure, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or *Hazardous Products Regulations* for products intended for the workplace.